

Attorney Docket: 052775-0311431

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT
APPLICATION OF: David SCHMIDT
SERIAL NO.: 10/669,596
FILING DATE: September 25, 2003
ART UNIT : 1611
EXAMINER GHALI, I. A. D.
FOR: BIOMOLECULAR WEARABLE APPARATUS

REPLY BRIEF UNDER 37 C.F.R. § 41.41

Mail Stop Appeal Brief - Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Examiner's Answer mailed May 11, 2009 ("Answer"),
Appellant submits a Reply Brief pursuant to 37 C.F.R. § 41.41.

It is not believed that any fees are due in this case. However, the Director is
hereby authorized to charge any additional fees that may be due, or credit any
overpayment of same to Deposit Account No. 033975 (Ref. No. 052775-0311431).

REQUIREMENTS OF 37 C.F.R. §41.41

I. 37 C.F.R. § 41.37(c)(1)(iii) – STATUS OF CLAIMS

Pending: Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 36, 38, 42, 58, and 59 are pending.

Cancelled: Claims 2, 4, 7-9, 12, 13, 15, 17, 19, 21, 23, 35, 27-33, 35, 37, 39-41, and 43-57 have been cancelled without prejudice or disclaimer.

Rejected: Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 38, 42, 58, and 59 stand rejected.

Withdrawn: Claim 36 has been withdrawn from examination.

Allowed: No claims have been allowed.

On Appeal: The rejection of claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 38, 42, 58, and 59 is appealed.

II. 37 C.F.R. § 41.37(c)(1)(vi) – Grounds of Rejection to be Reviewed on Appeal.

Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, 42, 58, and 59 currently stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,475,514 to Blitzer *et al.* ("Blitzer"); claim 26 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Blitzer in view of U.S. Patent No. 6,558,695 to Moo-Young *et al.* ("Moo-Young"); and claim 34 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Blitzer in view of U.S. Patent No. 6,558,695 to Luo *et al.* ("Luo"). These rejections constitute legal error, and should be reversed upon review.

III. 37 C.F.R. § 41.37(c)(1)(vii) – ARGUMENT

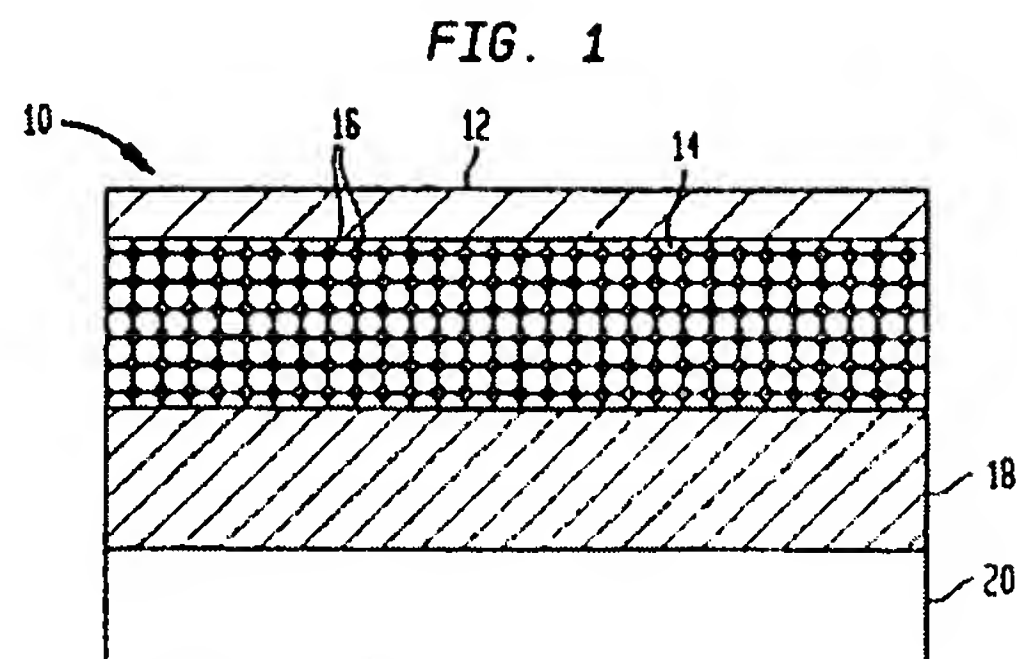
For the sake of brevity, Appellant addresses below only the rejections of claims in which the Answer raised new issues and/or made mischaracterizations of the teachings of the references, the subject matter of the claims, and/or Appellant's positions that Appellant has not adequately addressed in the Appeal Brief. The exclusion from these Arguments of some of the rejections addressed specifically in the Arguments of the Appeal Brief should not be viewed as acquiescence on the part of Appellant. Instead, Appellant believes that the arguments provided in the Appeal Brief with respect to the rejections not addressed here are sufficient in showing legal error.

A. CLAIM 1 (and its dependent claims)

The rejection of claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 38, and 42 under 35 U.S.C. § 102 based on Blitzer constitutes clear legal error at least because the Examiner has failed to demonstrate that Blitzer discloses all of the features of the claimed invention. For example, claim 1 recites *inter alia* the following features, which are not disclosed in the sections of Blitzer relied on by the Examiner:

...at least one enclosure for enclosing said at least one organic material and said at least one substrate, wherein said at least one enclosure comprises an adhesive for adhering said at least one enclosure to said subject's body and wherein said at least one enclosure **prevents said at least one organic material from direct contact with said subject's body while said at least one enclosure is adhered to said subject's body using said adhesive.**

The patch disclosed in the cited sections of Blitzer (illustrated in FIG. 1 of Blitzer, reproduced below), is a transdermal patch that releases materials in solution contained within the patch into the blood stream of the body through the epidermis [see, e.g., Blitzer, c. 2, ll. 25-34]. As such, the cited sections of Blitzer do not disclose an "enclosure [that] **prevents said at least one organic material from direct contact with said subject's body while said at least one enclosure is adhered to said subject's body using said adhesive**" [the Appeal Brief, pp. 6-7].



In response to the arguments presented in the Appeal Brief, the Examiner contends (1) that claim 1 does not exclude the transdermal patch described in Blitzer, (2) that claim 1 does not exclude the delivery of the recited "organic materials" through the skin as described in Blitzer, (3) that a foam matrix described in Blitzer and the adhesive described as affixing the matrix to the skin of a subject anticipate the "at least one enclosure" of claim 1, and (4) that the recitation of "said enclosure prevents organic material from direct contact with [sic] subject body" is intended use and does not result in a structural difference between the claimed invention and Blitzer. Each of these contention constitutes legal error.

1. Claim 1 Is Not Anticipated By A Transdermal Patch.

The recitations of claim 1 are not anticipated by a transdermal patch like the one disclosed in Blitzer that allegedly releases an "organic material including a Left-Handed molecule" enclosed within "at least one enclosure" of the patch into the epidermis of a subject.

The plain meaning of "transdermal" is "through or by way of the skin" ["transdermal." *The American Heritage® Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Company, 2004. 23 Jun. 2009. <Dictionary.com <http://dictionary.reference.com/browse/transdermal>>.] The Examiner acknowledges that transdermal patches are generally understood to be medicated adhesive patches that are placed on the skin to deliver a dose of medicament through the skin [the final Office Action, p. 3 (emphasis added)]. So the meaning of the term "transdermal patch" is not in dispute.

The Examiner alleges that reference in the specification of the instant application to embodiments of a “wearable object” including a “dermal patch” precludes Appellant from arguing that the claimed invention is not anticipated by a transdermal patch. This is erroneous because a “dermal patch” is not necessarily the same thing as a “transdermal patch.” A “dermal patch” does not necessarily release a medicament (or other solution) into the body of the wearer. Instead, the term “dermal patch,” at most, denotes a patch that is (or can be) adhered to and/or worn on the skin of the wearer. The Examiner provides no evidence to the contrary.

The express recitations of claim 1 (reproduced above) recite that the “at least one enclosure prevents said at least one organic material from direct contact with said subject’s body while said at least one enclosure is adhered to said subject’s body using said adhesive.” By definition, a transdermal patch releases the solution contained therein into the body of the subject wearing the patch through the skin. this requires contact with and passing through the skin. As such, assuming that the solution carried in and released by the transdermal patch described in Blitzer includes an “organic material” having “a Left-Handed molecule” (as the Examiner alleges is the case with the patch of Blitzer), the patch at best controls the amount and/or rate of the alleged “organic material” that contacts and passes through the skin of the subject. Because this transdermal patch must release the material into the skin of the subject “while said [patch] is adhered to said subject’s body,” it must permit “direct contact” between the material and “said subject’s body” upon adhesion to “said subject’s body.” The Examiner provides no evidence to the contrary. This is the opposite of what is claimed.

Therefore, by definition, the features of claim 1 reproduced above are not anticipated by a transdermal patch that releases an “organic material including a Left-Handed molecule” into the epidermis of a subject. Thus, the Examiner’s contention that claim 1 does not exclude the transdermal patch described in Blitzer constitutes legal error. It is unsupported by any evidence or rational legal argument.

2. Claim 1 Is Not Anticipated By Disclosure Of A Patch In Blitzer That Requires Delivery Of The “Organic Material” Contained Within The “Enclosure” To The Skin Of A Subject.

Claim 1, and in particular the features of claim 1 reproduced above, is not anticipated by a reference, such as Blitzer, that requires the delivery of “organic material including a Left-Handed molecule” from within an “enclosure” into the skin of a subject.

To deliver the “organic material” through the skin of the subject, the “organic material” delivered to and/or through the skin would necessarily come into “direct contact” with the skin. The “at least one enclosure” of the “apparatus” recited in claim 1 “prevents said at least one organic material from direct contact with said subject’s body while said at least one enclosure is adhered to said subject’s body using said adhesive.” As such, claim 1 precludes delivery to the subject’s skin of “organic material” contained within the “at least one enclosure... while said at least one enclosure is adhered to said subject’s [skin].”

Therefore, the features of claim 1 reproduced above are not anticipated by the disclosure of patches, like the patch of Blitzer, that require delivery of an organic material contained therein to and/or through the skin of a subject while the patch is adhered to the skin of the subject. Thus, the Examiners allegation that claim 1 does not exclude the delivery of the recited “organic materials” through the skin as described in Blitzer constitutes legal error.

3. The Foam Matrix And Adhesive Of The Patch Of Blitzer Does Not Anticipate The “Enclosure” Of Claim 1.

The foam matrix 16 and adhesive layer 18 shown in FIG. 1 of Blitzer above do not anticipate the “enclosure” of claim 1 at least because neither the foam matrix 16 nor the adhesive layer 18 “prevent[] said at least one organic material from direct contact with said subject’s body while said at least one enclosure is adhered to said subject’s body using said adhesive.”

The Answer alleges that the foam matrix 16 “reads on the substrate” [p. 8]. The Answer then alleges that the foam matrix 16, in combination with adhesive layer 18, further anticipates the “enclosure” recited in claim 1 [*id.*]. However, Blitzer specifically states that the foam is permeable to the “athletic supplement” (which allegedly anticipates the “organic material” of claim 1)[c. 18, ll. 26-28]. Thus, the foam is not capable of preventing the “athletic supplement” from directly contacting any external

substance or surface (because the supplement can pass straight through the foam). Similarly, Blitzer discloses that when release liner 20 is removed from the adhesive 18 and adhesive 18 is secured to the skin of a subject, the "athletic supplement" is released into the skin of the subject through the adhesive [c. 9, ll. 64-65]. As such, neither foam matrix 16 nor adhesive layer 18 "prevents said at least one organic material from direct contact with said subject's body while said at least one enclosure is adhered to said subject's body using said adhesive."

Therefore, neither foam matrix 16 nor adhesive layer 18 of Blitzer anticipate the "at least one enclosures" recited in claim 1. Thus, the Examiner's contention that the foam matrix described in Blitzer and the adhesive described as affixing the matrix to the skin of a subject anticipate the "at least one enclosure" of claim 1 constitutes legal error.

4. The Recitation Of "Said At Least One Enclosure Prevents Said At Least One Organic Material From Direct Contact With Said Subject's Body While Said At Least One Enclosure Is Adhered To Said Subject's Body Using Said Adhesive" In Claim 1 Is Not Merely Intended Use.

Where claim language states a condition that is material to patentability, it cannot simply be ignored [*Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed.Cir. 2005)].

The recitation of "said at least one enclosure prevents said at least one organic material from direct contact with said subject's body while said at least one enclosure is adhered to said subject's body using said adhesive" defines characteristics of the "said at least one enclosure." In order to "prevent[the] organic material from direct contact with said subject's body while said [] enclosure is adhered to said subject's body," the "at least one enclosure" must include structure that isolates the organic material from contacting the body of the subject while the claimed apparatus is being worn by the subject. Thus, this recitation of claim 1 is material to patentability, and does not merely recite intended use of the apparatus.

As further evidence of the materiality of the above-quoted recitation of claim 1 to patentability, the device of Blitzer relied on by the Examiner does not anticipate the "at least one enclosure" at least because the device disclosed in Blitzer lacks structure

capable of “prevent[ing the] organic material from direct contact with said subject’s body while said [] enclosure is adhered to said subject’s body.” The patch of Blitzer is configured such that adhesive layer 18 (shown in FIG. 1 *supra*) is pressure sensitive, and the patch releases the athletic supplement (allegedly anticipating the “organic materials”) into the skin of the subject whenever the patch is adhered to the subject [c. 9, ll. 64-65].

Therefore, the “at least one enclosure” of claim 1 is structurally different from the components of the patch described in Blitzer because the patch described in Blitzer does not have the features positively recited with respect to the “at least one enclosure.” For at least this reason, the failure of the Examiner to give patentable weight to the recitation of “said at least one enclosure prevents said at least one organic material from direct contact with said subject’s body while said at least one enclosure is adhered to said subject’s body using said adhesive” constitutes legal error.

5. Conclusion

The sections of Blitzer relied on by the Examiner do not anticipate at least the “at least one enclosure” recited in claim 1 [see, e.g., the Appeal Brief, pp. 6-7, and *supra*]. In the Answer, the Examiner contends that Blitzer does anticipate the “at least one enclosure” because (1) claim 1 allegedly does not exclude the transdermal patch described in Blitzer, (2) claim 1 allegedly does not exclude the delivery of the recited “organic materials” through the skin as described in Blitzer, (3) a foam matrix described in Blitzer and the adhesive described as affixing the matrix to the skin of a subject allegedly anticipate the “at least one enclosure” of claim 1, and (4) the recitation of “said enclosure prevents organic material from direct contact with [sic] subject body” is allegedly intended use and does not result in a structural difference between the claimed invention and Blitzer. Each of these allegations are erroneous for at least the reasons presented above. Therefore, the sections of Blitzer relied on by the Examiner do not anticipate all of the features of claim 1. For at least this reason, the rejection of claim 1 and its dependent claims constitutes legal error and must be reversed.

B. CLAIM 58

The rejection of claim 58 under 35 U.S.C. § 102 based on Blitzer constitutes clear legal error at least because the Examiner has failed to demonstrate that Blitzer discloses all of the features of the claimed invention. For example, claim 58 recites *inter alia* the following features, which are not disclosed in the sections of Blitzer relied on by the Examiner:

...wherein said at least one enclosure prevents said at least one organic material from direct contact with said subject's body and wherein the beneficial biological effect for the subject is accomplished while said at least one organic material and said substrate are enclosed in said at least one enclosure.

The cited sections of Blitzer do not disclose these features of claim 58 at least because in order for the patch described in Blitzer to provide a user with a "beneficial biological effect," the patch must release an athletic supplement (alleged by the Examiner to anticipate the "organic material") into the body of the use through the skin. Thus, with the patch of Blitzer, the "organic material" is not enclosed in "at least one enclosure" while the "beneficial biological effect... is accomplished" because at least a portion of the "organic material" must be inside the body of the subject to bring the "beneficial biological effect" about [the Appeal Brief, pp. 7-8].

In response to this argument, the Examiner contends that "[t]he intended use recited by claim 58 including 'said enclosure prevents organic materials from direct contact with subject body' is met by the references because the claim requires 'prevention of *direct* contact' and not 'absolute prevention contact,' and the adhesive layer disclosed by Blitzer prevents direct contact of organic materials with the skin. Thus, the enclosure of the organic material as taught by Blitzer prevents *direct* contact" [the Answer, p. 12 (emphasis in original)]. Not only do these allegations constitute legal error [see, e.g., *supra* with respect to claim 1], but they are not responsive to Appellant's arguments in the Appeal Brief. Assuming *arguendo* that the patch disclosed in Blitzer were capable of "prevent[ing]... direct contact [between the organic material and] said subject's body," the patch described in Blitzer and the athletic supplement contained therein would still not be disclosed as accomplishing a "beneficial biological effect for

the subject is [] while [the athletic supplement is] enclosed in said at least one enclosure." Therefore, the sections of Blitzer relied on by the Examiner do not disclose the features of claim 58 reproduced above. For at least this reason the rejection of claim 58 based on the cited sections of Blitzer constitutes legal error and must be reversed.

C. CLAIM 59

The rejection of claim 59 under 35 U.S.C. § 102 based on Blitzer constitutes clear legal error at least because the Examiner has failed to demonstrate that Blitzer discloses all of the features of the claimed invention. For example, claim 59 recites *inter alia* the following features, which are not disclosed in the sections of Blitzer relied on by the Examiner:

...at least one wearable object comprising at least one enclosure for said at least one organic material and said at least one substrate, wherein said at least one enclosure **prevents said at least one organic material from direct contact with said subject's body while said at least one wearable object is worn on said subject's body.**

When the patch disclosed in Blitzer is adhered to the body of a user, the patch releases an athletic supplement (alleged by the Examiner to anticipate the "organic material") into the body of the user through the user's skin [see, e.g., *supra* and the Appeal Brief, pp. 8-9]. Blitzer does not disclose any other mechanism for "wearing" the patch other than adhering the patch to the body. Therefore, for at least the reasons presented above with respect to claim 1, the sections of Blitzer relied on by the Examiner do not disclose the features of claim 59 reproduced above. For at least this reason the rejection of claim 59 constitutes legal error and must be reversed.

CONCLUSION

For at least the foregoing reasons, Appellant respectfully requests that the rejection of each of claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, 36, 38, 42, 58, and 59 be reversed.

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Respectfully submitted,

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